DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 14, 2015

Exactech, Incorporated
Mr. Thomas McNamara
Regulatory Affairs Specialist
2320 North West 66th Court
Gainesville, Florida 32653

Re: K150458
Trade/Device Name: Exactech® Equinoxe® Reverse Shoulder 46x21mm Glenosphere
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: April 14, 2015
Received: April 16, 2015

Dear Mr. McNamara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150458

Device Name
Exactech® Equinoxe® Reverse Shoulder 46x21mm Glenosphere

Indications for Use *(Describe)*
The Equinoxe Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Exactech® Equinoxe® Reverse Shoulder 46x21mm Glenosphere
Special 510(k) – 510(k) Summary

Sponsor: Exactech®, Inc
2320 NW 66th Court
Gainesville FL, 32653

Phone: (352) 377-1140
Fax: (352) 378-2617

FDA Establishment Number 1038671

Date: April 14, 2015

Contact Person: Thomas McNamara
Regulatory Affairs Specialist
Telephone: (352) 327-1140
Fax: (352) 378-2617

Proprietary Name: Exactech® Equinoxe® Reverse Shoulder 46x21mm Glenosphere

Common Name: Reverse Shoulder Arthroplasty

Classification Name:

Shoulder Prosthesis, Reverse Configuration (21 CFR Section 888.3660, Class II, Product Code PHX).

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

Name	Manufacturer	510(k) Number
Equinoxe Reverse Shoulder System	Exactech, Inc	K063569

Indication for Use:

The Equinoxe Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

Device Description

The proposed Exactech Equinoxe Reverse Shoulder 46x21mm Glenosphere represents a modification of the predicate Exactech Equinoxe Reverse Shoulder 46x25mm Glenosphere cleared in K063569. Both the predicate and proposed devices have the same intended use, general design features and basic fundamental scientific technology. The only difference between the predicate and the proposed device are the following dimensional modifications:

1. Reduced Lateral Offset – The proposed glenosphere has a lateral offset of 21mm, which is 4mm shorter than the predicate 46x25mm glenosphere.

Exactech® Equinoxe® Reverse Shoulder 46x21mm Glenosphere
Special 510(k) – 510(k) Summary

These modifications are proposed to provide another glenosphere option to the existing glenospheres cleared in K063569.

Testing:
The following engineering analyses were conducted to demonstrate substantial equivalence of the proposed Exactech Equinoxe Reverse Shoulder 46x21mm Glenosphere to the predicate Exactech Equinoxe Reverse Shoulder Glenospheres:

- Glenoid Loosening and Cyclic Fatigue Testing
- Analysis Of Deltoid Abductor Moment Arms
- Range of Motion Analysis

Substantial Equivalence Conclusion:
Results of engineering studies referenced in this 510(k) submission demonstrate the proposed Exactech Equinoxe Reverse Shoulder 46x21mm Glenosphere are substantially equivalent to the cleared Exactech Equinoxe Reverse Shoulder 46x25mm Glenosphere.